Statement of
Donald W. Rucker, M.D.
on behalf of the
National Electrical Manufacturers Association (NEMA)

before the
Subcommittee on Health
Energy and Commerce Committee
U.S. House of Representatives

"Use of Imaging Services:
Providing Appropriate Care for Medicare Beneficiaries"

Tuesday, July 18, 2006

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Mr. Chairman and Members of the Subcommittee:

My name is Donald Rucker. I am a practicing emergency physician and serve as Vice President and Chief Medical Officer of Siemens Medical Solutions USA. I am speaking today on behalf of the National Electrical Manufacturers Association.

NEMA is the largest association representing medical imaging manufacturers in the world. It represents companies whose sales comprise more than 90 percent of the global market for X-ray imaging, computed tomography (CT), radiation therapy, diagnostic ultrasound, nuclear medicine imaging, magnetic resonance (MRI), and medical imaging informatics equipment.

NEMA is also the world's primary standards-development organization for medical imaging equipment. Such standards establish commonly-accepted methods of design, production, and distribution for medical imaging products. Sound technical standards benefit the user and patient, as well as the manufacturer, by improving safety, fostering efficiencies, and assisting the purchaser in selecting and obtaining the appropriate product. We have been setting standards for 75 years.

I want to thank the Chairman for conducting this important hearing on imaging. On behalf of NEMA, I also want to thank the Subcommittee members who have taken steps to ensure continued beneficiary access to critical imaging services.

Summary and Overview

In my testimony today, Mr. Chairman, I wish to leave the Subcommittee with several points:

Scientific Advances are the Primary Reason for Imaging Growth: The primary drivers of imaging utilization are the dramatic scientific and technical advances that allow physicians to see soft tissues and organs inside the human body. The power of imaging to offer more precise and less-invasive care has sparked what can only be described as a fundamental transformation in medicine. Physicians can now use imaging for more conditions, for more patients, and for a much broader array of purposes than ever before. Modern imaging devices today are sophisticated

computers, and the imaging power behind them continues to grow in parallel with the growing computing power that drives so many other sectors of the economy.

Medical Imaging Has Become a Standard of Care: Given this new ability to make specific diagnoses—rather than educated clinical guesses—before treating a patient, physicians have incorporated medical imaging into practice patterns across medical conditions and diseases. In fact, imaging has become a standard of modern care for virtually all major medical conditions and diseases. This includes cancer, stroke, heart disease, trauma, and abdominal and neurological conditions.

Utilization Growth Arises from Complex Causes: No one can doubt that financial incentives play a role in the use of imaging. But the impact of these incentives pales in comparison to these broad, patient-centered changes. Interestingly, growth in utilization is remarkably similar across medical specialties that can bill for imaging and those that cannot. Growth in utilization is also remarkably consistent across organ systems, suggesting that a desire to address patient care questions is behind the growth, not practice changes by specific medical specialties.

Continued Innovation and Patient Access Require Informed Policies: Public policies that influence the use of medical imaging—including reimbursement decisions such as the Deficit Reduction Act of 2005—must take into account this fuller view and richer context of utilization growth. Basing imaging reimbursement policy almost purely on year-over-year growth rates overlooks these deeper realities and patient desire for diagnostic certainty.

I will elaborate on each of these today, Mr. Chairman, before turning to our policy recommendations on reimbursement of imaging and issues directly related to growth in the use of imaging.

Scientific Advances are the Primary Reason for Imaging Growth

As a first step, it is important to explore why imaging has become such a driving force in how physicians practice and how medical delivery is structured.

For centuries, physicians diagnosed patients by using the physical examination. With the advent of plain film x-rays a little over a century ago, physicians could see bones and outlines, as well as shadows of some organs such as the heart and the lungs. Today, with modern imaging devices, physicians can see every single soft tissue, organ, and clinically significant blood vessel. Complemented by a parallel, computing-based revolution in genomics, we simply have the opportunity to take care of patients in entirely new ways. In this context, it does not seem surprising that Medicare is seeing rapid growth in these clinical practices.

How has medical imaging technology transformed health care?

Redefining Care: Advances in imaging have provided physicians with new tools to improve care and do so in new ways. As a result, they use imaging in more clinical situations, for more diseases, and for more patients.

- Diagnosis of heart disease was once confined to a stethoscope and an EKG. Today, physicians use imaging procedures such as cardiac catheterization, CT angiography, cardiac ultrasound, and nuclear imaging to address heart disease. These foster early diagnosis and treatment and improved survival.[1] With intravascular ultrasound, the very basis of coronary artery care has moved from treating "hardening of the arteries" to addressing "vulnerable soft plaque".

- For decades, cancer physicians were limited to guesswork and indirect evaluations in judging the effect of cancer drugs on a tumor. Today, PET scans allow them to visualize the tumor on a individual cellular level, determine how well cancer drugs are working, and calibrate therapy to the patient's exact circumstances.[2]

New Information for Diagnosis and Planning: Imaging has also brought about significant change by providing physicians with vast amounts of new information and visualization for every body part. This allows them to diagnose disease and plan treatment more effectively and confidently.

- CT and MRI now allow physicians see the blood vessels in the brain and the precise location of a stroke—reducing guesswork—and guide them in choosing between surgery or clot-busting drugs.[3]

- Physicians use CT and MRI, rather than surgery, to visualize and pinpoint brain tumors and aneurysms—even view them in 3D.[4] This gives them critical information about the approach to treatment, sparing as much normal brain tissue as possible.

As these examples also show, the power of medical imaging is increasingly blurring the lines between diagnosis and treatment delivery.

Less-Invasive Treatment: Medical imaging has also transformed medicine by enabling physicians to provide medical treatments deep within the body without

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[1] See Mowatt G, Brazzelli M, Murray A, Fraser C, Vale L. Systematic review of single photon emission computed tomography (SPECT) myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction. Nucl Med Commun. 2005 Mar;26(3):217-29. Also see Alan S, Ulgen MS, Ozturk O, Alan B, Ozdemir L, Toprak N. Relation between coronary artery disease, risk factors and intima-media thickness of carotid artery, arterial distensibility, and stiffness index. Angiology. 2003 May-Jun;54(3):261-7. Also see *The Value of Investment: Better Care, Better Lives*, by MedTAP International, February 2004.

[2] "Positron-Emission Tomography and Assessment of Cancer Therapy," Juweid, ME, Cheson, BD, *New England Journal of Medicine*, 2006 354: 496-507.

[3] "Diagnosis as a Guide to Stroke Therapy," *The Lancet*, Vuadens P, Bougousslavsky J, 1998: (suppl III) 1014. Also see "Practice Guidelines: Use of Imaging in Transient Ischemic Attacks/Acute Stroke," A Report of the Stroke Council, American Heart Association, *Stroke*, 1997; 28: 1480-1497; and "Stroke Tests," American Stroke Association at www.strokeassociation.org, and

[4] See White PM, Wardlaw JM, Easton V. Can non-invasive imaging accurately depict intracranial aneurysms? A systematic review. Radiology. 2000 Nov;217(2):361-70.

surgery, blood loss, or their related risks. So care is easier, complications fewer, and recovery is faster. As a result, patients who may have avoided surgery or whose health conditions did not allow surgery may now elect to receive care.

- Screening for abdominal aortic aneurysms now allows elective surgery or even minimally invasive aortic stent placement preventing largely fatal aortic aneurysm ruptures.[5]

- Physicians can now use image-guided embolization to correct uterine fibroid tumors without a hysterectomy. This permits patients to get back to work in two weeks, rather than six.

- Physicians can use stereotactic radiosurgery which targets very narrow but extremely powerful beams of radiation on small brain tumors and early metastases. The procedure requires no hospitalization and substitutes for brain surgery.

Substitution for Other Health Care Costs: Innovations in medical imaging also provide physicians with new capabilities to substitute imaging for other interventions or procedures, including observation days in the hospital.

- Physicians can use ultrasound to guide them in placing large-bore intravenous catheters in central veins—substituting for blind guesses about where the vein is located. The result is reduced pain and complications—and shorter hospital stays.[6]

- With high resolution CT scans, physicians can now precisely diagnosis appendicitis. As recently as several years ago, the standard of care for possible appendicitis included hospital admissions to observe for clinical deterioration and exploratory surgery to enable the surgeon to look directly at the appendix and see whether it needed to be removed.[7]

- CT scans can tell physicians whether a pulmonary embolism has developed in the lung, thereby reducing the need to thread a catheter through the heart to reach the lung.[8]

- Intensity-modulated radiation therapy allows physicians to pinpoint tumor location and "sculpt" each beam of radiation, thus avoiding harm to surrounding healthy tissue.[9]

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[5] "Community-Based, Nonprofit Organization-Sponsored Ultrasonography Screening Program for Abdominal Aortic Aneurysms Is Effective at Identifying Occult Aneurysms," Ogata T, Arrington S, Davis PM Jr, Sam AD 2nd, Hollier LH, Tromp G,Kuivaniemi H., *Ann Vasc Surg*. 2006 Apr 27; [Epub ahead of print]

[6] "Ultrasonic Locating Devices for Central Venous Cannulation: Meta-Analysis," Daniel Hind, et al, *The British Medical Journal*, Volume 327, 16 August 2003

[7] "CT Evaluation of Appendicitis and its Complications: Imaging Techniques and Key Diagnostic Findings," Pinto Leite N, Pereira JM, Cunha R, Pinto P, Sirlin C.,AJR Am J Roentgenol. 2005 Aug;185(2):406-17. Review.

[8] "Multidetector-Row Computed Tomography in Suspected Pulmonary Embolism," Perrier, et. al., *New England Journal of Medicine*, Vol 352, No 17; pp. 1760-1768, April 28, 2005. Also, "Clinical Validity of a Negative Computed Tomography Scan in Patients with Suspected Pulmonary Embolism: A Systematic Review," Quiroz, et al., *Journal of the American Medical Association*, Vol 293, No 16; pp. 2012-2017, April 27, 2005.

New Settings of Care: Medical imaging is now smaller and more portable, enabling care in a variety of new settings such as physician offices and imaging centers. For patients, the result is convenience and easier access—increasing the likelihood they will get the tests, treatments, and follow-up they need.[10]

- Shrinking ultrasound machine size allows physicians to diagnose cardiovascular, obstetrical, abdominal, and many soft tissue problems in independent imaging facilities, physician offices, and other non-hospital locations as well as at the patient's bedside. Hand-carried ultrasound machines are used in emergency rooms, ambulances, and even on the battlefield.[11]

- Similar changes are occurring in other imaging technologies, including digital radiography, CT, and MRI. These technologies now allow diagnosis and treatment in a variety of non-hospital settings.

The Computer Revolution and Imaging: Modern imaging devices are in large part sophisticated computer systems that perform incredible transformations of signals acquired via sound waves, x-ray beams, or radio frequency waves and proton spins. Computing power over the last 40 years has in fact grown as described by "Moore's Law", a remarkable prediction by Gordon Moore, one of the founders of Intel, who stated back in 1965 that, as far as he could see, computing power would double every 18 months. For Medicare patients and physicians, this has come to mean that every two to three years, entirely new aspects of the body come into focus and, what was before a clinical guess is now a precise answer from an imaging study.

Mr. Chairman, I want to stress that any of these trends individually would have been enough to bring about important improvements in medical care. Taken together, however, they have brought deep change to the health delivery system:

- Diagnosis is earlier than ever.

- Physicians have more information and insight.

- Care is less invasive and less painful.

- Access to tests and treatments is easier as imaging procedures are available in convenient settings.

- Patient outcomes—from fewer complications to saved lives—are dramatically improved.

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[9] See "High Dose Intensity Modulated Radiation Therapy for Prostate Cancer: Early Toxicity and Biochemical Outcome in 772 Patients," by Zelefsky MJ, Fuks Z, Hunt M, Yamada Y, Marion C, Ling CC, Amols H, Venkatraman, ES, Leibel S, in *International Journal of Radiation Oncology, Biology, Physics*, Volume 53, No. 5; pages 1111-1116, August 2002. Also see "Cancer in the Crosshairs," Brown E, *Forbes*, p. 364, October 28, 2002.

[10] See "Travel Distance to Radiation Therapy and Receipt of Radiotherapy Following Breast-Conserving Surgery," Athas WF, et. al., *Journal of the National Cancer Institute*, Vol. 92, No. 3, February 2, 2000, pp. 269-271.

[11] See "The Incredible Shrinking Ultrasound Machine," Elsberry, RB, *Imaging Economics*, Nov. 2001.

- System-wide savings and efficiencies abound.

Medical Imaging Has Become a Standard of Care

Another factor in the transformation of medicine is that imaging has become a standard of modern care for virtually all major medical conditions and diseases.

Heart Disease

One of the most dramatic contributions that imaging has made over the past 30 years has been its role in the significant reductions in mortality and morbidity of heart disease.[12] Advances in cardiac imaging have enhanced every aspect of cardiac care, including screening, diagnosis, treatment, and follow-up monitoring—providing detail unachievable even a decade ago.[13] Cardiac catheterization, ultrasound, and CT scanning provide physicians with vital information and precise images of blood flow, artery blockages, and heart functioning.[14] This information allows physicians to make earlier, more accurate diagnoses and to better target therapy. Also, medical imaging facilitates coronary angioplasty which has become the therapy of choice for opening clogged arteries and has been shown superior to drugs in more than 20 clinical trials.[15]

Advances in imaging continue to offer new insights and detail about cardiac activity. Today, multi-slice CT provides rapid images of coronary artery plaque and precise visualization of clogged arteries without use of invasive catheters.[16] In addition, MRI and nuclear imaging scans show functioning of the heart muscle at the cellular level allowing effective treatment of CHF, one of Medicare's most costly illnesses.

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[12] See *The Value of Investment: Better Care, Better Lives*, by MedTAP International, February 2004. Also see "Trends in Heart Attack Treatment and Outcomes, 1975-1995, Literature Review and Synthesis," by Paul Heidenreich and Mark McClellan, in *Medical Care Output and Productivity,* edited by David M. Cutler and Ernst R. Berndt, University of Chicago Press, 2001.

[13] See Lewin Report, p. ii. Also see Alexanderson E, Granados N, Gomez-Martin D, Ricalde A, Meave A. [Evaluation of coronary artery disease by myocardial perfusion imaging in women] Arch Cardiol Mex. 2005 Jan-Mar;75(1):35-41. Also see Mowatt G, Brazzelli M, Murray A, Fraser C, Vale L. Systematic review of single photon emission computed tomography (SPECT) myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction. Nucl Med Commun. 2005 Mar;26(3):217-29.

[14] See "American College of Radiology Clinical Statement on Noninvasive Cardiac Imaging," Weinreb, JC, et. al., Radiology, June 2005, Vol. 235, pp. 723-727.

[15] See "Primary Angioplasty Versus Intravenous Thrombolytic Therapy For Acute Myocardial Infarction: A Quantitative Review of 23 Randomized Trials," by Keeley EC; Boura JA; and Grines CL; in *The Lancet*, Vol 361, No 9351, Jan 4, 2003. Also see "A Comparison of Coronary Angioplasty with Fibrinolytic Therapy in Acute Myocardial Infarction," by Andersen et al, in *The New England Journal of Medicine*, Vol 349, No 8; 733-742, 2003.

[16] "Roles of Nuclear Cardiology, Cardiac Computed Tomography, and Cardiac Magnetic Resonance: Assessment of Patients with Suspected Coronary Artery Disease," Berman, DS, et. al., *Journal of Nuclear Medicine*, V 47, No 1, January 2006, pp. 74-82. Also see "How New Heart-Scanning Technology Could Save Your Life," by Christine Gorman and Alice Park, *Time*, Sept 5, 2005, pp. 58-71.

Stroke

Medical imaging has made modern stroke therapy possible through early, accurate diagnosis and new treatment options.[17] Numerous imaging technologies, such as ultrasound and MRI, provide high-resolution images of the vascular system, and the brain to identify blockages or the thickening of the artery lining, thus allowing stroke prevention. CT scans, diffusion-weighted imaging, and PET scans aid physicians in assessing whether carotid endarterectomy is appropriate—a surgery that removes plaque from the arteries that supply blood to the brain.[18]

When stroke hits, imaging tests such as CT and MRI provide rapid information about the nature and location of stroke and the extent of brain injury, allowing physicians to make well-informed judgments rapidly.[19] This information enables physicians to differentiate between ischemic stroke, involving a blockage in the arteries, and hemorrhagic stroke, which involves rupture or loss of blood. With this information, physicians can prescribe cost- and life-saving thrombolytic therapy—a drug treatment for ischemic brain attack.[20] Or they can use imaging to guide delicate surgical procedures to close ruptured arteries. Imaging also enables use of microcoil stents to correct brain aneurysms without open surgery, thus reducing patient hospital stays by half and allowing patients to recover months earlier.[21]

Lancet study identifies productivity gains from stroke therapy

Let me add one more small, but important point, with regard to the role of imaging in diagnosing and treating stroke. A study published this past April in *The Lancet*, one of the premier medical journals in the world, reported that three NIH studies on techniques for diagnosing and treating stroke—in which medical imaging plays a critical role in guiding physician decisions—led to a net economic benefit to society of roughly $8 billion in the 10 years following completion of the studies.[22] These are the benefits in dollar terms that arose from use of the approaches suggested in the studies, minus the total treatment costs.

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[17] See "Stroke Treatment: Time is Brain," Hill MD, and Hachinski V, *The Lancet*, 1998; 352 (suppl III) 1014. Also see "Practice Guidelines: Use of Imaging in Transient Ischemic Attacks/Acute Stroke," A Report of the Stroke Council, American Heart Association, *Stroke*, 1997; 28:1480-1497.

[18] See "Cost Effectiveness of Carotid Endarterectomy Clinical Study," Nussbaum ES, Heros RC, Erickson DL, *Neurosurgery*, 38; 237-244; 1996. Also see *The Value of Investment in Health Care: Better Care, Better Lives*, MedTap International, p. 34, 2004.

[19] "Evidence-Based Neuroimaging in Acute Ischemic Stroke," Vo DK, Lin W, Jin-Moo L, *Neuroimaging Clinics North America*, 13 (2003), 167-183.

[20] "Cost-Effectiveness of Tissue Plasminogen Activator for Acute Ischemic Stroke. NINDS rt-PA Stroke Study Group," Fagan SC, Morgenstern LB, Petitta A, Ward RE, Tilley BC, Marker JR, Levine SR, Broderick JP, Kwiatkowski TG, Frankel M, Brett TG, and Walker MD, in *Neurology*, 50, 4: 883-890.

[21] "Surgical and Endovascular Treatment of Unruptured Cerebral Aneurysms at University Hospitals," by Johnston SC, Dudley RA, Gress DR, and Ono L , *Neurology*, 1999; 52:1799. Also see "Endovascular and Surgical Treatment of Unruptured Cerebral Aneurysms: Comparison of Risks," by Johnston SC, Wilson CB, Halbach W, Higashida RT, Dowd CF, McDermott MW, Applebury CB, Farley TL, Gress DR, *Annals of Neurology*, 2001, May; 49(5): 682-4. Also see, "International Subarachnoid Aneurysm Trial (ISAT) of Neurosurgical Clipping Versus Endovascular Coiling in 2143 Patients with Ruptured Intracranial Aneurysms: A Randomised Comparison of Effects on Survival, Dependency, Seizures, Rebleeding, Subgroups, and Aneurysm Occlusion," Molyneux AJ, Kerr RS, Yu LM, Clarke M, Sneade M, Yarnold JA, Sandercock P, *The Lancet*, Vol. 366, Issue 9488, September 3, 2005, Pages 809-817.

[22] "Effect of a U.S. National Institute of Health Programme of Clinical Trials in Public Health and Costs," Johnston SC, et. al., The Lancet, Vol.367, pp. 1319-1327, April 22, 2006.

These treatments—in this case, use of clot busting drugs following stroke onset and carotid endarterectomy to clear clogged arteries to the brain—would not be possible without the sophisticated imaging provided by CT, MRI, ultrasound, and other modalities. In addition, a separate study published online by *The Lancet* on July 4, 2006, added a new prospect for even greater value.[23] It found that advanced MRI is effectively able to extend the time window—which has traditionally been understood to be three hours following the onset of symptoms—during which certain patients can benefit from clot-busting drugs. This holds the potential for dramatic new savings in lives and costs.

Cancer

Medical imaging is also a primary tool in the battle against cancer. Over the past two decades, advances in medical imaging have dramatically improved cancer diagnosis and treatment.[24]

Earlier detection of breast cancer through mammography has reduced death rates in the U.S. and other countries,[25] with ultrasound and MRI aiding in diagnosis and treatment. CT, MRI, and PET scans give physicians vital information about the location and nature of cancer to aid in treatment planning. And computer-aided detection, or CAD, systems enhance the ability of mammography to detect breast cancer in its early stages.[26] Minimally invasive imaging procedures allow biopsies of breast, bone, and other tissue without open surgery, dramatically reducing infections, complications, and recovery time.[27]

Sophisticated new radiation treatment systems provide targeted radiation therapy that matches the tumor shape, but protects surrounding tissue. The result: better success rates, quicker pain relief, and fewer complications.[28]

PET and other cell-metabolism specific nuclear scans also allow physicians to identify cancer cells when they number in the hundreds of cells rather than waiting for the cancer cell doubling to the millions of cells that are needed to be seen with other modalities.

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[23] "MRI versus CT-based Thrombolysis Treatment Within and Beyond 3-hour window after Stroke Onset," Kohrmann, M; Lancet Neurology, 2006, published online, July 4, 2006

[24] "Molecular Imaging in Cancer: Future Directions and Goals of the National Cancer Institute," Hoffman JM, Menkens AE, *Academic Radiology 2000*, Vol 7, No 10, October 2000, p.905. Also see, "Imaging in Cancer: A National Cancer Institute 'Extraordinary Opportunity,'" Hoffman, JM, *Neoplasia*, Vol. 2, No.1/2, January-April, 2000.

[25] "Effect of Screening and Adjuvant Therapy on Mortality from Breast Cancer," Berry, DA, et. al., *The New England Journal of Medicine*, October 27, 2005, pp.1784 - 1792. Also, "Effects of Chemotherapy and Hormonal Therapy for Early Breast Cancer on Recurrence and 15-year Survival: An Overview of the Randomised Trials," Early Breast Cancer Trialists' Collaborative Group (EBCTCG), *The Lancet*, Vol. 365, May 14, 2005, pp. 1687-1717.

[26] "Screening Mammograms: Interpretation with Computer-aided Detection—Prospective Evaluation," Morton, MJ, *Radiology*, Vol. 239, No. 2, pp. 375-383, May, 2006.

[27] See "Diagnosis of Primary Bone Tumors with Image-Guided Percutaneous Biopsy: Experience with 110 Tumors," by Jelinek JS, Murphey MD, Welker JA, Henshaw RM, Kransdorf MJ, Shmookler BM, Malawer MM, *Radiology* 2002; 223; 731-737.

[28] See, "High Dose Intensity Modulated Radiation Therapy for Prostate Cancer: Early Toxicity and Biochemical Outcome in 772 Patients," by Zelefsky MJ, et. al., *International Journal of Radiation Oncology, Biology, Physics*, Volume 53, No. 5; pages 1111-1116, August 2002.

Physician Practice Guidelines Specifically Recommend Imaging

The central role that medical imaging plays in addressing disease is captured in medical practice guidelines developed by many medical specialty societies, including the American College of Radiology and the American College of Cardiology. The guidelines reflect clinical recommendations developed by the specialty physician groups themselves on how best to diagnose or treat specific medical conditions. They are based upon proven and widely accepted standards and evidence.

Recent examples of such guidelines include:

- Guidelines by the American Urological Association recommending use of ultrasound to assess prostate size or abnormalities, guide minimally invasive kidney biopsies, and examine the bladder for suspected bladder stones.[29]

- Guidelines by the American Heart Association and the American College of Cardiology recommending use of ultrasound, CT, and other imaging technologies to diagnose peripheral arterial disease.[30]

- Recommendations of the U.S. Preventive Services Task Force—the nation's pre-eminent preventive services panel—to use ultrasound screening to detect abdominal aortic aneurysms in elderly male smokers.[31] The USPSTF has long-established recommendations on the use of imaging to detect breast cancer and colorectal cancer.

Governmental bodies also frequently underscore the importance of imaging in diagnosis and treatment. Many of the national coverage decisions issued by Medicare over the past 18 months have involved medical imaging—PET scanning in particular. In 2005, the Medicare program covered PET for Alzheimer's disease and for diagnosing and determining the stage of esophageal, colorectal, head and neck cancer, and non-small-cell lung cancer, as well as lymphoma and malignant melanoma.[32] Medicare also agreed to provide payment for use of PET for virtually all other types of cancer if provided as part of a clinical trial or a national registry, such as the National Oncologic PET Registry.[33] Medicare coverage clears the way for use among the program's 40 million beneficiaries.

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[29] American Urological Association, "Guidelines for Ultrasound Utilization," accessed May 8, 2006, at http://auanet.org/about/policy/education.cfm#ultrasound.
[30] ACC/AHA Practice Guidelines for the Management of Patients with Peripheral Arterial Disease (Lower Extremity, Renal, Mesenteric, and Abdominal Aortic): Executive Summary," Hirsch AT, et. al., *Circulation*, March 21, 2006, pp. 1474-1547.
[31] "Screening for Abdominal Aortic Aneurysm: A Best-Evidence Systematic Review for the U.S. Preventive Services Task Force," Fleming C, et. al. *Annals of Internal Medicine*, Feb 2005, Vol. 142, No. 3, pp. 203-211; and "Screening for Abdominal Aortic Aneurysm: Recommendation Statement, U.S. Preventive Services Task Force," *Annals of Internal Medicine*, Feb 2005, Vol. 142, No. 3, pp. 198-202.
[32] "Positron-Emission Tomography and Assessment of Cancer Therapy," Juweid ME, and Cheson, BD, *The New England Journal of Medicine*, Vol. 354, No. 5, Feb. 2, 2006, pp. 496-507.
[33] See http://www.cancerpetregistry.org/index.htm.

Physicians Say Imaging is Most Important Innovation

In light of the impact of imaging on the practice of medicine, Mr. Chairman, it is not surprising that it has been rated highly by physicians and medical journals alike.

A 2001 study published in the policy journal *Health Affairs* asked 225 leading general internists to rank the relative importance of 30 medical innovations in terms of their value in improving patient care.[34] These physicians, a group who do not do imaging themselves, overwhelmingly picked two imaging technologies—CT and MRI—as the most significant medical innovation. The next highest choice, a heart drug, was rated much lower. Of the top five innovations chosen by these physicians, three involved imaging: CT and MRI, image-guided balloon angioplasty, and mammography.

While this survey focused on general internists, the same broad adoption of imaging has occurred among medical specialty physicians as well. This includes oncologists, surgeons, cardiologists, internists, and emergency room physicians, among others. In March 2005 testimony, a coalition of more than 20 physician specialty groups characterized the importance of imaging in the way they practice in this way:

> "In addition to traditional diagnostics employing medical imaging, we now use imaging to guide minimally invasive treatments and to track ongoing treatment protocols through judicious use of medical imaging. We are enabled as physicians to adjust patient care plans mid-therapy to achieve the best possible outcomes. Several specialist groups intimately integrate medical imaging in the most delicate and intricate aspects of their care. The prudent use of medical imaging in the actual treatment regimen is not only excellent medicine: it also manages short- and long-term costs by minimizing wasteful and ineffective treatments."[35]

It is not surprising that *The New England Journal of Medicine* called imaging one of the top 11 innovations of the past 1,000 years—ranking it alongside such milestones as the invention of anesthesia, the discovery of the cell, the understanding of genetics, and the synthesis of antibiotics.[36]

Utilization Growth Arises from Complex Causes

Unfortunately, these broad, patient-centered changes that underlie growth in imaging are not often heard in policy discussions about utilization. As noted earlier, utilization growth is judged almost entirely on the size of the year-to-year change, not on whether the reasons behind it are sound or unsound. In fact, increase in the number of imaging procedures per patient is one of the primary metrics used to

34 "Physicians' Views of the Relative Importance of Thirty Medical Innovations," Victor R. Fuchs and Harold C. Sox, Jr., *Health Affairs*, Volume 20, Number 5, September/October, 2001.
35 Williams, Testimony before the U.S. House Ways and Means Committee, March 17, 2005
36 "Looking Back on the Millennium in Medicine," the Editors, New England Journal of Medicine, Volume 342, pp. 42-49, January 6, 2000.

demonstrate excessive utilization.[37] Yet it is this very metric that captures the transformation of medicine brought about by imaging—physicians use it more broadly, in more patients, for more conditions because it improves care.

In addition, it is widely accepted that financial incentives for physicians—usually in the form of self-referral—are behind the increase in imaging growth. Yet, detailed analysis of Medicare payment data done for NEMA suggests that the growth in imaging utilization has been remarkably consistent across all specialties and procedures whether or not there is an opportunity for "self-referral." In particular, the percentage of dollars spent on each of the top five imaged areas—the heart, spine, brain, extremities and abdomen—has stayed remarkably constant. This suggests that—rather than performing new studies largely for reimbursement—physicians are using better studies to answer age-old clinical questions, such as why the patient is not able to talk or move or is in pain. Notably, these imaging patterns cross all specialties—those that have the opportunity for self-referral and those for whom ordering, explaining, arranging, and tracking imaging studies done by someone else is purely an additional cost, not specifically reimbursed.

To complicate the issue of utilization further, the costs associated with increases in utilization are often overstated. In its *March 2005 Report to the Congress: Medicare Payment Policy*, the Medicare Payment Advisory Commission argued that utilization of imaging technologies was increasing out of proportion to growth in other health care services and that these increases contributed to steep cuts in physician reimbursement through a budgeting mechanism known as Medicare's Sustainable Growth Rate (SGR) formula.[38]

In fact, imaging costs have grown at about the same rate as other portions of health care spending. With regard to the SGR, imaging services grew 4.6 percent per year faster than other services that were included in the SGR mechanism. But a study done for the National Electrical Manufacturers Association found that more than half of that was due solely to a shift in imaging services from hospital outpatient departments to physician offices and other non-hospital settings. When this "site-of-service" shift—from hospital to non-hospital settings—is taken into account, imaging services grew about 2.0 percent faster than other services.[39]

A 2005 study by the Lewin Group found that when growth in imaging costs are compared to growth in all Medicare Part B services, imaging grew at roughly the same rate. From 1999-2003, the average annual growth in all Medicare Part B services across providers was 7.8 percent, while the comparable growth in imaging was 8.7 percent—only about 0.9 percentage points faster.[40]

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[37] See "Report to the Congress: Medicare Payment Policy," Medicare Payment Advisory Commission, March 2005, Washington, D.C.
[38] Ibid.
[39] See "NEMA Cautions on Misinterpreting Medical Imaging Growth under SGR," National Electrical Manufacturers Association press release, April 20, 2006, accessed May 22, 2006, at http://www.nema.org/media/pr/20060420a.cfm.
[40] "Issues in the Growth of Diagnostic Imaging Services: A Case Study of Cardiac Imaging," The Lewin Group, May 3, 2005, p. 20.

Similarly, a study of overall hospital costs over the seven-year period of 1996-2002 at Massachusetts General Hospital found that medical imaging costs rose more slowly than overall hospital costs. The study also found that use of imaging was linked to shorter hospital stays.[41]

Utilization Growth Often Means Offsetting Savings

In this regard, Mr. Chairman, I want to underscore that, despite frequent assertions to the contrary, medical imaging reduces costs and creates new efficiencies in health delivery and improved productivity in patients. In these cases, greater utilization means greater savings.

- The American Heart Association journal *Stroke* reported that a "scan-all" strategy for stroke patients ultimately saved money—when compared to later, or reduced, use of CT scans for such patients—because the information from the scans led to better diagnoses that led to better outcomes and shorter hospital stays.[42] Thus, greater use of CT scans, and greater expenditures on CT scans as a result, translated into dollar savings overall.

- Physicians at Massachusetts General Hospital reported in the *American Journal of Roentgenology* that increased use of state-of-the-art CT imaging in treating facial trauma patients led to a reduction in overall imaging costs of 22 percent per patient between 1992 and 2002. The primary explanation for the findings, according to the researchers, is that CT cost less than it did 10 years earlier, did more, and increasingly substituted for X-ray examinations, which dropped by 50 percent over the period.[43]

- A study from *Radiology* found that image-guided breast biopsy costs roughly a third of what a surgical biopsy does. This minimally invasive procedure uses ultrasound or mammography images to locate a suspicious lump or nodule in the breast. It takes one-fifth the amount of time as surgical biopsy, reduces complications, and allows women to return to normal activities in half the time that it takes after open surgery.[44] In Medicare patients, use of this procedure is increasing, while use of more invasive procedures, such as surgery, is declining.

In each of these cases—and the peer-reviewed literature contains many more examples like them, for virtually all imaging modalities—the number of imaging procedures per patient increases. Yet in each case, more utilization of imaging is better, not worse, because it represents cost-savings. This underscores the point that increases in utilization do not automatically equate with inappropriate utilization.

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[41] "Diagnostic Imaging Costs: Are They Driving up the Costs of Hospital Care?", Beinfeld MT, Gazelle GS, *Radiology*, 2005; 235:934-939.
[42] "Immediate Computed Tomographic Scanning of Acute Stroke is Cost-Effective and Improves Quality-of-Life," Wardlaw, JM; Seymour JC; Keir S; Lewis S, and Sandercock P, *Stroke*, November, 2004, pp. 2477-2483.
[43] Trends in the Use of CT and Radiography in the Evaluation of Facial Trauma, 1992-2002: Implications for Current Costs," Turner BG, Rhea JT, Thrall JH, Small AB, Novelline RA; *American Journal of Roentgenology*, 2004; 183: 751-754.
[44] "Core-Needle and Surgical Breast Biopsy: Comparison of Three Methods of Assessing Cost," Jeffrey H. Burkhardt and Jonathan H. Sunshine, *Radiology*, 212:181-188, 1999.

Another complicating issue is that the budgeting and accounting systems that public and private payers use for imaging procedures fail to take into account any savings that arise from the use of that imaging. Thus, savings that offset other costs—such as substitution of minimally invasive breast biopsies for open surgery—are never reflected, while the increase in the number of imaging studies performed is tabulated. The result is a skewed picture of both imaging utilization and its costs. It is interesting to note that, in exploring the potential for Medicare payment analysis based on grouping care into all-inclusive episodes, even MedPAC acknowledges that paying for isolated pieces of care is fundamentally flawed.[45] NEMA believes that disproportionately forcing cutbacks in imaging when it can drive cost savings in other areas of care is inappropriate.

Mr. Chairman, this is our view of the forces behind utilization of imaging. To be sure, inappropriate utilization exists. It is a serious issue and we do not wish to underplay it. But as we look at the real world of health delivery, there isn't the degree of wasteful, out-of-control utilization that many observers suggest. Instead, what is prominent is a glimpse of the power of science to offer better views inside the human body and greater insight about a patient's condition.

Continued Innovation & Patient Access Requires Informed Policies

DRA Cuts will Harm Patients, Providers, and Even Medicare

It is in this broader context of forces underlying utilization growth that that we offer these observations about the payment reductions of the DRA.

We view the DRA imaging cuts as excessive and unjustified. Given their size, these reductions will set off a chain reaction that will force many physicians to discontinue or greatly reduce the availability of imaging services. In turn, patients will find it harder to get care, will have to travel further, and will face long delays as they seek care in hospital outpatient departments. I have attached to my testimony a short policy brief summarizing our view of the DRA cuts. It was prepared by the Access to Medical Imaging Coalition, of which NEMA is a member.

To ensure continued quality care, we urge Congress to pass H.R. 5704, the Access to Medicare Imaging Act. The measure would impose a two-year delay on the cuts while the Government Accountability Office analyzes the likely impact of the cuts on Medicare beneficiaries, especially those living in rural areas. We see this as sensible health policy and prudent fiscal policy.

[45] "Report to Congress: Increasing the Value to Medicare," Medicare Payment Advisory Commission, June, 2006.

DRA cuts will harm Medicare beneficiaries

The Subcommittee should be aware of the breadth and significance of systemic issues that will arise from the DRA cuts.

- First, utilization will not be improved. These are budget cuts, nothing else. They affect imaging procedures without regard to whether such procedures are overused, inappropriately used, or underused.

- Second, the rate reductions bear no relationship to the real-world costs of providing imaging services. Some 80 percent of the services subject to the DRA caps will fall to levels below the office-based cost of providing the service. Many will fall to less than half of these real costs. This stands in sharp contrast to efforts by CMS, as described by Administrator Mark McClellan just last week, to ensure that payment decisions "accurately reflect the cost of providing quality care."[46]

- Third, costs are dictated by the site of care. The DRA ignores legitimate differences in the costs of providing imaging services in different settings—specifically hospital outpatient departments versus physician offices and independent imaging facilities. The legislation does this despite the fact that both Congress and Medicare have long recognized and adjusted for these differences. In fact, the DRA largely presumes that the hospital outpatient and the physician payment systems are interchangeable. They are not. They are very distinct systems with unique designs that reflect the nature of care delivered in very different settings. Rates on the physician fee schedule reflect the costs of specific procedures; hospital outpatient rates reflect the estimated cost of a bundle of different services, adjusted to reflect the expected severity of the patients who will likely need that care. Mixing these systems, especially to hunt for the lowest rates, poses threats to office-based treatments and tests that go well beyond the DRA imaging cuts themselves.

- Fourth, the DRA reductions contradict efforts in CMS and Congress to add reason and predictability to Medicare payment systems, including value-based purchasing proposals. It seems ironic that, at a time when CMS states that its goals for the Medicare physician payment system are to make rates "understandable, intuitive and stable," that the DRA imposes reductions that contradict this intention.[47]

- Finally, the DRA cuts may actually *increase* inappropriate utilization. The reason is the cuts are so deep they create incentives for providers to increase the number of procedures to compensate for extreme financial shortfalls.

Future diffusion of important imaging advances requires reimbursement policies that are equitable and reflective of the resources required to provide high-quality,

[46] Mark B. McClellan Remarks to InHealth, the Institute for Health Technology Studies, July 10, 2006.
[47] Physician Practice Expense Proposed Rule, Federal Register, June 2006.

appropriate care. The Deficit Reduction Act of 2005 reductions to imaging payments will slow – maybe greatly – the adoption of medical technologies that free patients of the older, more invasive alternatives which often require longer recoveries and hospital stays.

Policies: NEMA Should Participant in Standards-Setting for Medical Imaging

I want to add one final note in closing, Mr. Chairman. If Congress decides the development of quality or performance standards is necessary to address use of medical imaging, NEMA should play a central role.

NEMA is not only an association of imaging manufacturers, it is also a standards-setting organization. For the past 75 years, NEMA has developed hundreds of medical imaging standards for product quality, safety, and performance.

- NEMA developed a standard for ultrasound equipment enabling the physician or sonographer to monitor the acoustic output display in real time, during an ultrasound examination. This helps minimize the ultrasound exposure, while maximizing the diagnostic information that can be acquired from the exam.

- NEMA developed a performance standard and quality control guidelines for single photon emission computed tomography (SPECT) devices used in nuclear medicine, to inform clinical users whether their SPECT devices are performing properly, and therefore suitable for use with patients.

- NEMA successfully developed, and continues to update, one of the most significant standards in improving efficiency and communications in health care delivery. The Digital Information and Communications in Medicine (DICOM) standard established a common digital "language" to facilitate the interchange of information between digital imaging computer systems in medical environments.

NEMA knows the technology. We know how it is used. We understand how to set standards and maintain them. NEMA needs to be at the table.

Conclusion

Let me conclude my remarks today, Mr. Chairman, with these final thoughts.

Perhaps at its most basic level, the increased use of medical imaging reflects the human desire to know—with more certainty—what is wrong, or why something hurts, or whether a dangerous disease is present. Medical imaging devices are the ultimate digital cameras that can help answer those questions. And the ability to look inside the human body with these tools—in new ways, with more precision, and with confidence in the result—arises from advances in computing technology and, in essence, science itself. Because computer power doubles roughly every 18 months,

we can expect—and hope--that these technical and technological advances to continue.

Mr. Chairman, we believe that it is short-sighted to base imaging reimbursement policy—and particularly our broader attitudes about imaging utilization—on year-over-year growth rates overlooking these deeper realities, desires, and needs. We believe that the starting place for finding sound policies to manage imaging utilization must begin with these fundamental realities.

Attachment

Access to Medical Imaging Coalition

Protecting and Preserving Access to Quality Imaging Services for our Nation's Medicare Patients

Imaging Cuts in Deficit Reduction Act 2005 Will Harm Patients and Physicians

ISSUE: Severe, last minute payment cuts in medical imaging in the Medicare physician fee schedule included in the Deficit Reduction Omnibus Reconciliation Act of 2005 (DRA) will lead to a wide range of adverse, unintended consequences for Medicare beneficiaries and providers.

BACKGROUND: Section 5102 of the DRA directs severe reductions in payments for many imaging services under the Physician Fee Schedule (PFS). Under this provision in the DRA, effective January 1, 2007, the payment for the technical component (e.g., equipment, non-physician personnel, supplies, and overhead) of an imaging service will be set at the Hospital Outpatient Department (HOPD) payment rate, if the PFS payment rate is higher.

CONCERNS: This change in Medicare payment policy raises a number of disturbing issues such as:

- **Rushed and Inadequate Process** – Neither Congress, nor MedPAC, nor any other public forum has held a public hearing or meeting on this proposal. This proposal has received no public comment or testimony.

- **Disproportionately Large Cuts for Imaging** – The cuts enacted for imaging by the DRA comprise roughly one-third of the total Medicare savings in the bill. Yet imaging only comprises roughly one-tenth of Medicare spending. Examples of these cuts include:

  - **Ultrasound** - Reimbursement for ultrasound guidance procedures, performed as part of a minimally invasive biopsy for the diagnosis of breast cancer (a biopsy method which saved the Medicare program $88 million from 2001 – 2003), would be reduced by 35 percent.
  - **PET / Nuclear Medicine** - Reimbursement for PET/CT exams used to diagnose cancerous tumors and determine the effectiveness of cancer treatment would be reduced by upwards of 50 percent (an unprecedented cut for a new technology whose HCPCS code was just provided by CMS in April 2005).
  - **DEXA** - Reimbursement for bone densitometry studies necessary for the diagnosis of women at risk for osteoporosis (a recently enacted Medicare screening benefit) would be reduced by over 40%.
  - **MRI** - Reimbursement for MR angiography of the head used to detect the location of aneurysms would be reduced by 42%.

- **A Failure to Recognize the Fundamental Differences between the costs associated with practicing medicine in a physician's office, and practicing medicine in a hospital outpatient department** - The different payment formulas for each site of service are specifically designed by Congress to take into account the unique differences and costs of providing care in each setting. Linking reimbursement under the PFS system to the HOPD system ignores real-world costs in personnel, rent, and supplies that physicians in non-hospital settings must deal with daily.

- **Limiting Beneficiary Access to Critical Imaging Services** – These cuts have the very strong potential to drive imaging from the physician office and free-standing facilities back into hospital outpatient departments, thus limiting Medicare beneficiaries' access to nearby imaging services that allow for more timely diagnosis and initiation of treatment.

- **Longer Wait Times for Medicare Patients** - On average, patients already wait 10 days to two weeks for non-urgent imaging services in the hospital outpatient department. Reduced access to imaging services in the physician's office and in free-standing imaging centers could increase these wait times dramatically.

- **Reduced Access For Medicare Patients in Rural Areas** - Beneficiaries may be forced to drive long distances for needed imaging services if providers reduce or eliminate imaging locally. Also physicians may choose not to invest in telemedicine equipment that allows specialists at distant locations to help interpret a patient's scan —again harming rural access.

SOLUTION: Please support HR 5704 to delay implementation of DRA Sec. 5102 for two years, while the GAO conducts a thorough study of the impact on patient access and services.